UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,160	05/24/2007	Helge H. Rasmussen	U 016502-0	8069

140 7590 12/18/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
PHILLIPS, WELDON PATRICK	
ART UNIT	PAPER NUMBER
4121	
MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,160	05/24/2007	Helge H. Rasmussen	U 016502-0	8069

140 7590 12/18/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
PHILLIPS, WELDON PATRICK	
ART UNIT	PAPER NUMBER
4121	
MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,160	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	WELDON PHILLIPS JR.	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application for patent entered the national stage in the United States of America under 35 U.S.C. 371 from PCT/AU2005/000590 claiming priority from Australia Application No. 2004902179.

Claims 1-25, as amended, are now pending.

Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a "single general inventive concept" as required under PCT Rule 13.1 and 37 C.F.R. § 1.475(a). In accordance with 37 CFR § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1 and 2, drawn to methods of treating a condition characterized by abnormal myocardial cell Na^+, K^+ or Ca^{2+} ion levels with β_3 adrenoreceptor agonists;

Group II: Claims 3-14, drawn to methods of treating individuals suffering from or susceptible to heart failure or myocardial hypertrophy via administration of β_3 adrenoreceptor agonists;

Group III: Claims 15 and 16, drawn to methods of treating a condition characterized by abnormally high myocardial cell Na^+ ion levels with β_3 adrenoreceptor agonists;

Group IV: Claim 17 and 19, drawn to methods of making β_3 adrenoreceptor agonist-containing medicaments;

Group V: Claims 18 and 20-22, drawn to β_3 adrenoreceptor agonists and compositions thereof;

Group VI: Claim 23, drawn to a composition comprising β_3 adrenoreceptor agonists and β_1 and/or β_2 adrenoreceptor antagonists; and

Group VII: Claims 24 and 25, drawn to methods of effectuating myocardial cell Na^+ extrusion with one or more β_3 adrenoreceptor agonists.

2. As set forth in PCT Rule 13.1, the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). As stated in Rule 13.2, where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. Rule 13.2 defines special technical features as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention determination begins with a consideration of the claims in light of the description and drawings. Lack of unity of invention may be directly evident "a priori," or before considering any prior art when no special technical feature is common to each of the independent claims. Alternatively, lack of unity of invention may

only become evident "a posteriori," or after considering the claims in relation to the prior art.

3. In the instant application, the claimed inventions listed as Groups I through VII are not so linked as to form a "single general inventive concept" under PCT Rule 13.1 and 37 C.F.R. § 1.475(a), because they lack the same or corresponding special technical features. Applicant's vastly different claims are directed to: methods of treating three different populations of individuals with β_3 adrenoreceptor agonists (Groups I through III), methods of making β_3 adrenoreceptor agonist medicaments (Group IV – the examiner has assumed this was applicant's intent), β_3 adrenoreceptor agonists and compositions thereof (Group V), compositions comprising combinations of β_3 adrenoreceptor agonists and β_1 and/or β_2 adrenoreceptor antagonists (Group VI) and methods of using β_3 adrenoreceptor agonists to effectuate myocardial cell extrusion of Na^+ (Group VII).

Applicants indicate and examiner agrees that "β_3 adrenoreceptor agonists are known in the art" (page 13 of the Specification). Applicant's disclosure goes on to enumerate a vast plurality of β_3 adrenoreceptor agonists found throughout the art, each of which are "contemplated in the invention" (page 14). By way of example, the pharmacological effects on cardiac function of one of applicant's disclosed β_3 adrenoreceptor agonists, BRL35135, has been evaluated in human volunteers (Wheeldon, 1994, cited on applicant's IDS). Wheeldon anticipates the claims of Group V (18 and 20-22), which as disclosed do not present a contribution over the prior art or

share a special technical feature with the other Groups. It follows, therefore, that the claims are not so linked within the meaning of PCT Rule 13.2 as to form a single inventive concept over the prior art, and unity between Groups I through VII is broken. Because unity of invention is lacking, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

4. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined** even though the requirement may be traversed under 37 CFR § 1.143 **and (ii) identification of the claims encompassing the elected invention**, including any claims subsequently added.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR § 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the claimed inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the claimed inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the claimed

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other claimed inventions.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Elections of Species

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected, EACH of the following species elections is required:

a) *condition characterized by abnormal myocardial cell* Na^+, K^+ *or* Ca^{2+} *ion levels* (e.g. heart failure, myocardial hypertrophy, etc.), with claims 1 and 2 reading on this species;

b) β_3 *adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claims 1 and 2 reading on this species.

If Group II is elected, EACH of the following species elections is required:

a) *β_3 adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claims 3-14 reading on this species;

b) *β blockers* (e.g. nadolol (non-selective), metaprolol (β_1-selective), ICI118551 (β_2-selective), etc.), with claims 9-12 reading on this species;

c) *ACE inhibitors* (e.g. captopril, enalapril, etc.), with claim 14 reading on the species;

d) *aldosterone antagonists* (e.g. spironolactone, eplerenone, etc.), with claim 14 reading on the species; and

e) *β adrenoreceptor antagonists* (e.g. nadolol (non-selective), metaprolol (β_1-selective), ICI118551 (β_2-selective), etc.), with claim 14 reading on the species.

If Group III is elected, EACH of the following species elections is required:

a) *condition characterized by abnormally high myocardial cell Na^+ ion level* (e.g. heart failure, myocardial hypertrophy, etc.), with claims 15 and 16 reading on this species; and

b) *β adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claims 15 and 16 reading on this species.

If Group IV is elected, EACH of the following species elections is required:

a) *β_3 adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claims 17 and 19 reading on this species.

If Group V is elected, EACH of the following species elections is required:

a) *β_3 adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claims 18 and 20-22 reading on this species.

If Group VI is elected, EACH of the following species elections is required:

a) *β_3 adrenoreceptor agonists* (BRL37344, BRL35135, etc.), with claim 23 reading on this species; and

b) *β_1 and/or β_2 adrenoreceptor antagonists* (e.g. nadolol (non-selective), metaprolol (β_1-selective), ICI118551 (β_2-selective), etc.), with claim 23 reading on this species.

If Group VII is elected, EACH of the following species elections is required:

a) β_3 adrenoreceptor agonists (BRL37344, BRL35135, etc.), with claims 24 and 25 reading on this species.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1 and 2 in Group I, applicant is required to elect a single condition characterized by abnormal myocardial cell Na^+, K^+ or Ca^{2+} ion levels and a single β_3 adrenoreceptor agonist. As to claims 3-14 in Group II, applicant is required to elect a single β_3 adrenoreceptor agonist, a single β blocker, a single ACE inhibitor, a single aldosterone antagonist and a single β adrenoreceptor antagonist. As to claims 15 and 16 in Group III, applicant is required to elect a single condition characterized by abnormally high myocardial cell Na^+ ion level and a single β_3 adrenoreceptor agonist. As to claims 17 and 19 in Group IV, applicant is required to elect a single β_3

adrenoreceptor agonist. As to claims 18 and 20-22 in Group V, applicant is required to elect a single β_3 adrenoreceptor agonist. As to claim 23 in Group VI, applicant is required to elect a single β_3 adrenoreceptor agonist and a single β_1 and/or β_2 adrenoreceptor antagonist. As to claims 24 and 25 in Group VII, applicant is required to elect a single β_3 adrenoreceptor agonist. Upon Applicant's election of species, the result must provide a single chemical species, a single condition or disease to be treated or improved, etc. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 1 and 2 as to Group I, claims 3-14 as to Group II, claims 15 and 16 as to Group III, claims 17 and 19 as to Group IV, claims 18 and 20-22 as to Group V, claim 23 as to Group VI and claims 24 and 25 as to Group VII. The following claim(s) are generic: claims 1 as to Group I and claims 3, 4, 9, 12, 13 and 14 as to Group II, claim 15 as to Group III, claims 17 and 19 as to Group IV, claims 18 and 20-22 as to Group V, claim 23 as to Group VI and claim 24 as to Group VII.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) Each chemical species is a distinct chemical which lacks a special technical feature as disclosed in view of Wheeldon; and

b) Each disease or condition to be treated or improved has distinct pathologies, etiologies and thus lack a special technical feature.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

10. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed under 37 CFR § 1.143 **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

An election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR § 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WELDON PHILLIPS JR. whose telephone number is (571)-270-7673. The examiner can normally be reached Monday through Thursday &

every other Friday between 7:30 AM and 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WP/
Examiner, Art Unit 4121

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121